ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS®
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Dr. Mark Rohrbaugh
Director of the Office of Technology Transfer
Office of Intramural Research
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852

Dear Dr. Rohrbaugh:

We are writing on behalf of the Association of University Technology Managers (AUTM®), to comment on the petition to use the authority under the Bayh-Dole act to promote access to: (a) Ritonavir, supported by National Institute of Allergy and Infectious Diseases Contract no. AI27220; and (b) Latanoprost, supported by U.S. Public Health Service Research Grant Numbers EY 00333 and EY 00402 from the National Eye Institute, filed by Essential Inventions, Inc. with Secretary Thompson on January 29, 2004. AUTM® is a nonprofit association with membership of more than 3,200 technology managers and business executives who manage intellectual property at over 300 universities, research institutions, teaching hospitals and a similar number of companies and government organizations.

While the subject of delivering affordable health care is certainly a serious issue for the United States, we believe it must be addressed through other means. There are no expressed authorities in the Act or implementing regulations that would support the petitioner's position for Governmental actions such as those requested. As noted in 35 U.S.C. 200, the general description of the authorities reserved to the government are limited, "...to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of the invention..." (underlining added).

The general reservation of rights in the Government is specifically implemented in the march-in provision of 35 U.S.C. §203, which should not be read to be any broader than intended in the general reservation of 35 U.S.C. §200, which would be necessary to grant the requested march-in request. Indeed, such actions as proposed by the petitioner were never contemplated by the Congress and are not reflected in a proper understanding of the legislative history of the law. On the contrary, it is clear that such authorities would actually frustrate the stated policy and objectives of the Act to create incentives for commercial development by assuring, when necessary, an exclusive patent position (see 35 U.S.C. 200).

We believe that an NIH interpretation of the Bayh-Dole Act as advocated by Essential Inventions would disable the Act. The primary basis for the Act lies in the belief of individual action as opposed to government action and the power of the market. Most inventions resulting from government research are conceptual

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in nature and require significant investment by the private sector to bring them into practical application. This is particularly true of life science inventions requiring licensure by the Food and Drug Administration. Commercial concerns are unlikely to invest substantial financial resources in the commercial development of any invention, funded in part by the government, knowing that the government could challenge their competitive position after the product was introduced onto the market. As was the experience in the years before the passage of the Bayh-Dole Act, when government policy was to grant only non-exclusive licenses, no drugs for which the government held title were developed and made available to the public.

Currently, exclusive licenses of federally funded inventions are believed to be dependable. This dependability can be maintained only if all those involved in the process retain full confidence that the march-in remedy will be exercised only in those extraordinary circumstances clearly anticipated by the Act. In 1997, Harold Varmus, then Director of the NIH, recognized this potential when he rejected the march-in petition of CellPro after it lost a patent infringement suit brought by Johns-Hopkins University, Becton Dickinson and Baxter. In issuing his determination, he stated:

> *"The patent system, with its resultant predictability for investment and commercial development, is the means chosen by Congress for ensuring the dissemination and development for new and useful technologies. It has proven an effective means for the development of healthcare technologies."*

On May 13, 2003, after a detailed study of technology transfer mechanisms, the President's Council of Advisors on Science and Technology concluded:

> *"Existing technology transfer legislation works and should not be altered."*

Interpreting agency authority to exercise march-in rights as advocated by the petitioner would be a major alteration to the existing technology transfer legislation. Granting a march-in in this instance would, we believe, serve only a narrow interest and be contrary to the broader public interest the Act is intended to serve. While we do not wish to diminish the seriousness of the issue of delivering affordable health care we believe it must be addressed through other means and urge the NIH to reject Essential Inventions's petition.

Sincerely,

Patricia Harsche Weeks

Patricia Harsche Weeks
Immediate Past President
AUTM